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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/754,711	01/12/2004	Deborah Kim Glencross	025455-113	1340
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EXAMINER				
FORD, ALLISON M				
ART UNIT		PAPER NUMBER		
1651				
NOTIFICATION DATE		DELIVERY MODE		
02/10/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary

Application No.

10/754,711

Applicant(s)

GLENCROSS, DEBORAH KIM

Examiner

ALLISON M. FORD

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 3, 4 and 6-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5 and 14-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/21/2008 has been entered.

Claims 1, 2, 5 and 14-16 have been amended. Claims 1-16 remain pending in the current application, of which claims 3, 4 and 6-13 remain withdrawn from consideration pursuant to 37 CFR 1.142(b) as being directed to a non-elected invention. Election was made with traverse on 5/9/2005.

Claims 1, 2, 5 and 14-16 have been considered on the merits. All arguments have been fully considered and will each be addressed below, as appropriate.

Response To Arguments/Amendments

Applicants' arguments, in combination with the amendments, received 11/21/2008 have been fully considered, and are found sufficient to obviate the prior grounds of rejection. However, the amended claims do present a number of new issues under 35 USC 112, second paragraph. These issues were discussed in the interview of 1/7/2009, and are made officially of record below:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1, 2, 5 and 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, step (a) it is unclear what sample is being tested/defined by sub-steps (i)-(iii). It would be remedial to amend the language to make it clear one is 'determining the proportion of CD45+ white blood cells which are CD4+ lymphocytes *in a cell sample*'.

In claim 1, step (b), it is unclear how the cell counting is achieved (i.e. flow cytometry? hematology analyzer?)

Furthermore, in claim 1, step (b), option (i) "directly counting the proportion calculated in step a)(iii)" it is unclear if reference is being made to the proportion of CD45+ white blood cells or the proportion of CD4+ lymphocytes. It appears the option intends to require direct counting of the CD4+ lymphocytes; however this would appear to negate the need for the calculations of step (a). Clarification is required.

Claim 2 recites "step (a)(i) is performed by flow cytometry using a bead-based or volumetric-based counting method"; however step (a)(i) of claim 1 refers to defining a primary population of CD45+ white blood cells, not a counting step. It appears claim 2 should refer to the counting steps referenced in step (b)(2).

Claim 14 further limits claim 2 by defining the bead-based counting method; however, as above, because claim 2 does not appropriately limit parent claim 1, the limitation of claim 14 is also found indefinite.

Claim 15 is held as indefinite because claim 1, step (a) requires the cell populations to be defined via flow cytometry, thus the recitation in claim 15 that step (a)(i) is obtained using a hematology analyzer fails to correlate with the parent claim.

Claim 16 is held as indefinite because claim 1, step (a)(i) requires definition of a population of cells having a specific expression pattern (CD45+), this method of defining a specific population of cells gives a proportion, not an absolute value, thus the recitation in claim 16 that the population of all CD45+ cells be defined per volume of blood does not properly correlate. Furthermore, parent claim 1 no longer recites the cell sample is from blood, thus it is inappropriate to state such in claim 16.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALLISON M. FORD whose telephone number is (571)272-2936. The examiner can normally be reached on 8:00-6 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Allison M. Ford/
Examiner, Art Unit 1651